

HAND SANITIZER- alcohol gel

Whish Body Products

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

mentha piperita, isopropyl myristate, aminomethyl propanediol, carbomer homopolymer type c, aloe vera leaf

Package Label - Principal Display Panel


whish
POWERFULLY EFFECTIVE NATURALS
spearmint + eucalyptus
HAND SANITIZER
70%
ETHYL ALCOHOL
PARABEN FREE • SULFATE FREE • PHTHALATE FREE • DEA & TEA FREE
PETROCHEMICAL FREE • CRUELTY FREE • LEAPING BUNNY CERTIFIED
237 mL e 8 FL OZ


Drug Facts
Active ingredient(s): Ethyl Alcohol 70% v/v. Purpose: Antiseptic.
Use(s): Hand sanitizer to help reduce microbial presence that potentially can cause disease. For use when soap and water are not available.
Warnings: For external use only. Flammable. Keep away from heat or flame.
Do not use: In children less than 2 months of age or on open skin wounds.
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.
Directions: Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years of age when using this product to avoid swallowing.
Other information: Store between 15-30°C (59-86°F). Avoid freezing and excessive heat above 40°C (104°F).
Inactive ingredients: Water (Aqua), Isopropyl Myristate, Acrylates C10-30 Acrylates Crosspolymer, Aloe Barbadensis (Aloe Leaf Juice), Aminomethylpropanediol, Mentha Piperita (Peppermint) Oil.

WHISH IS DEDICATED TO THE DISCOVERY OF NATURAL INGREDIENTS WHICH ENABLE INTELLIGENT CHOICES FOR YOUR SKIN. WELCOME TO A GENTLE NEW WORLD.
TESTED ON US, NOT ANIMALS. MADE IN THE USA.
Whish Body Products, LLC Scottsdale, AZ 85260
WWW.WHISHBEAUTY.COM 8 12280 01681 3

DOCUMENT CONTROL

FILE: s+e_sanitizer_8oz_label_OT_ai

 = PMS 3262

 = BLACK

000 mL NDC: 00000-000-00

HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76224-7833
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	
MENTHA PIPERITA (UNII: 79M2M2UDA9)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Product Characteristics

Color	green (Spearmint and Eucalyptus)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76224-7833-8	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Whish Body Products (606576952)**Registrant** - Whish Body Products (606576952)**Establishment**

Name	Address	ID/FEI	Business Operations
Whish Body Products		606576952	manufacture(76224-7833)